

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*
Case No. 18-op-45090

*The County of Cuyahoga, et al. v. Purdue
Pharma L.P., et al.*
Case No. 17-op-45004

MDL No. 2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF CRAIG MCCANN**

TABLE OF CONTENTS

ARGUMENT.....	2
I. McCann’s Analysis Does Not Fit the Facts of the Case.....	2
A. There is No Basis for Plaintiffs’ Characterization of SMTT as an Estimate of the Suspicious Orders that Any Reliable SOM Program Would Identify.....	2
B. The Assumption is the Standard That McCann Actually Applied, Not SMTT.....	5
II. Plaintiffs Fail to Justify the Other Defects in McCann’s Analysis.....	7
CONCLUSION.....	8

TABLE OF AUTHORITIES

<i>Jack Henry & Assocs., Inc. v. BSC, Inc.</i> , 487 F. App'x 246 (6th Cir. 2012).....	3
<i>Masters Pharm., Inc. v. Drug Enforcement Administration</i> , 861 F.3d 206 (D.C. Cir. 2017)	3
<i>Miami Valley Paper, LLC v. Lebbing Eng'g & Consulting GMBH</i> , 2010 WL 11538131 (S.D. Ohio Jan. 22, 2010)	4

Plaintiffs’ defense of Dr. Craig McCann contains an untenable contradiction: Plaintiffs concede that no Defendant was actually required to use McCann’s Six Month Trailing Threshold (“SMTT”) or any other specific methodology from his report in their suspicious order monitoring (“SOM”) systems. Opp. 22, 27 (Dkt. 2112).¹ Indeed, Plaintiffs argue, the SMTT method merely provides an “estimate” of the magnitude of orders Defendants should have identified through a reliable SOM system, whatever its precise form—an argument premised on expert opinion that was never offered by McCann, Rafalski, or any other expert. *Id.* at 27-8. At the same time, however, their position *depends upon* there being an obligation to use the SMTT methodology, because that is the starting point for McCann’s assumption that Defendants “did not perform adequate due diligence” on orders that “triggered” that model. *Id.* at 13. If there is no requirement to use the SMTT method, and Defendants did not use it, then they appropriately would not have reviewed orders that would have been “triggered” by that method. There is obviously no requirement to “hold any subsequent orders” following those that appropriately were not flagged. *Id.* It is only by starting with the premise that Defendants *were required* to use that methodology that his assumption regarding subsequent orders can even begin to make sense.² But Plaintiffs do not— and cannot— defend that starting point, and therefore do not defend his calculation in any meaningful way.

Contrary to Plaintiffs’ attempt to minimize McCann’s analysis as some benign reference point for the jury to understand “the magnitude of suspicious orders that any reliable SOM program would have identified,” Opp. 27, the undisputed reality is that Plaintiffs intend to use McCann’s

¹ Plaintiffs refer to SMTT as “Methodology A.”

² As Defendants showed in their motion, and Plaintiffs do not contest, without that assumption the percentage of orders “flagged” by McCann would fall dramatically – in one Defendant’s case from *over 92%* of all orders to *under 6%*. See Mot. at 3 & n.14.

calculation as a measure of the “suspicious orders” Defendants allegedly shipped in violation of a legal duty. But that again presumes that Defendants were under a legal duty that Plaintiffs concede they cannot establish. The vast majority of the orders that Plaintiffs’ experts are characterizing as “suspicious orders” shipped into commerce are treated that way “*regardless of whether those orders would have independently been flagged as suspicious by a suspicious order methodology.*” Opp. 13 (emphasis added). They are only being characterized in that fashion because of a baseless initial assumption that the particular flagging methodology used by McCann is what makes an original order suspicious, and the failure to use his methodology to review that order makes all “subsequent orders” suspicious as well. *Id.* To allow these assumed violations of non-existent duties as evidence of Defendants wrongdoing would be farcical.

McCann’s opinions do not fit the facts of the case and should be excluded.

ARGUMENT

I. McCann’s Analysis Does Not Fit the Facts of the Case.

A. There is No Basis for Plaintiffs’ Characterization of SMTT as an Estimate of the Suspicious Orders that Any Reliable SOM Program Would Identify.

Plaintiffs do not dispute that orders flagged by McCann would be wholly irrelevant unless they reflect “suspicious orders.”³ At the same time, Plaintiffs concede that Defendants did not have a legal duty to use SMTT, the primary method McCann used to flag orders. Trying to thread this needle, Plaintiffs argue that “the fact that a Defendant could have used an alternative to [SMTT] does not render [SMTT] an unreliable methodology *for estimating the magnitude of suspicious orders that any reliable SOM program would have identified.*” Opp. 27. Put another way, Plaintiffs argue that while Defendants have no duty to use SMTT specifically, it is an appropriate standard because it flags roughly the same orders as would “any reliable SOM

³ Br. 2 (Dkt 1903).

program.” *Id.* That is a novel, but quantifiable proposition, one that assumes—and depends on—the existence of supportive expert opinion. Neither McCann nor Rafalski offer or provide a basis for such an opinion.

Both McCann and Rafalski acknowledged that other compliant methodologies may exist (a point Plaintiffs concede as well),⁴ but neither said anything that would suggest those methods would flag a comparable set of orders as SMTT. Plaintiffs tellingly do not cite to either expert’s report or deposition. Instead, they blame *Defendants* for failing to prove “that another ‘reliable method’ would have actually identified a significantly different set of orders.” Opp. 27. It is hornbook law that under *Daubert*, “[t]he *proponent* of the testimony bears the burden of proving admissibility.” *Jack Henry & Assocs., Inc. v. BSC, Inc.*, 487 F. App’x 246, 255 (6th Cir. 2012). It was not Defendants’ burden to disprove Plaintiffs’ experts’ opinions, especially one that was never even offered in the first place.⁵

Moreover, Defendants did not even need to disprove this unoffered, unsubstantiated opinion because Plaintiffs’ own experts already did. McCann himself compared the results of five “reliable methods,” Opp. 16–23, that, in fact, identified dramatically different sets of orders. For example, 92% of orders shipped by McKesson into Cuyahoga were deemed suspicious under SMTT (including McCann’s improper assumption), compared to 27.9% under Methodology C

⁴ McCann Tr. (Dkt. 1981-12) 269:19–270:1; Rafalski Rpt. (Dkt 1999-21) 404:23–405:2; Opp. 23, 27.

⁵ In a different section of their brief, Plaintiffs refer to the D.C. Circuit’s dicta in *Masters Pharm., Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) regarding the method on which SMTT purports to be based. Opp. 17. That dicta was offered without the benefit of the factual record (including DEA testimony) available here, which unequivocally refutes the panel’s suggestion that orders that meet SMTT’s criteria are unusual “as a matter of common sense and ordinary language.” Regardless, expert opinion is not reliable where its only basis, aside from the expert’s *ipse dixit*, is passing dicta in a judicial opinion.

(including his assumption).⁶ Nor can Plaintiffs argue that these dramatic differences are due to the fact that they reflect a comparison of one method that complies with the CSA—SMTT—against four that do not. Even if it were true that SMTT was the only compliant method of the five, neither McCann nor Rafalski even attempt to compare the set of orders flagged by SMTT with orders flagged by other **compliant** methods, and thus there is no valid basis for the argument. *See Miami Valley Paper, LLC v. Lebbing Eng'g & Consulting GMBH*, 2010 WL 11538131, at *5 (S.D. Ohio Jan. 22, 2010) (“The lack of ... comparative analysis renders the validity of [plaintiff’s expert’s] testimony ... wholly suspect.”).

Similarly, Rafalski’s opinions show that different methodologies would yield different sets of flagged orders depending on the variables taken into account. In his report, he opines that registrants should calculate thresholds “based on the history of usage of [a] customer for a period *of at least 12 months*,”⁷ whereas SMTT calculates thresholds based on the previous *six months*. Assuming a baseline either of 6 or 12 months is appropriate, the difference likely would result in different thresholds and thereby flag different orders.⁸ Rafalski also describes other variables that registrants are required to consider in setting thresholds; SMTT incorporates **none** of them.⁹

For these reasons, there is no basis for Plaintiffs to argue that SMTT is a reliable estimate of suspicious orders that “any reliable SOM program would have identified,” which was Plaintiffs’ only argument in defense of McCann’s use of a methodology they concede Defendants had no

⁶ Rafalski Rpt. (Dkt 1999-21), at 41–43.

⁷ Rafalski Rpt. at 37–38.

⁸ In McCann’s illustration of SMTT, if a customer’s hydrocodone orders in the first six months were 5,000; 10,000; 7,000; 8,000; 9,000; and 9,500, then the threshold for the next month would be 10,000. *See* McCann Rpt. (Dkt. 1999-13), at 56. If the next six months were 11,000; 12,000; 15,000; 20,000; 18,000; and 14,000, then **all** of those orders would flag under SMTT, whereas **none** would flag under the 12-month guideline Rafalski identifies in his report.

⁹ Rafalski Rpt. at 37–38.

duty to use. Opp. 27. Because there is no basis for Plaintiffs to equate SMTT with a duty actually owed by Defendants, there is no credible basis for McCann to present orders flagged by SMTT as a measure of the “suspicious orders” Defendants allegedly shipped, and Plaintiffs’ defense of McCann falls apart. Plaintiffs should not be permitted to argue to the jury that nearly every order Defendants shipped was “suspicious” based on a methodology that does not reflect or even estimate a duty actually owed by Defendants.

B. The Assumption is the Standard That McCann Actually Applied, Not SMTT.

In any event, Plaintiffs’ attempt to characterize SMTT as a reliable estimate of suspicious orders is a distraction because only a tiny fraction of orders even satisfied SMTT’s criteria. The rest flagged due to the “no due diligence” assumption McCann was instructed to apply. Plaintiffs do not dispute that, for example, out of the 92.9% of Cardinal orders that McCann flagged, *only* 5.3% exceeded the six-month trailing threshold. Br. 4. Thus, if SMTT reliably estimates the magnitude of suspicious orders, then one would expect the number of flagged orders to be around 5.3%, not 92.9%. Because McCann did not really apply the standard Plaintiffs try to pass off as a reliable estimate of suspicious orders, there is no justification for presenting his inflated numbers to the jury.

Moreover, Plaintiffs offer no meaningful response to Defendants’ argument that McCann’s application of the “no due diligence” assumption—which drives the number of orders from 5.3% to 92.9%—is unfounded and prejudicial. *See* Br. 11–12. Plaintiffs dismiss these arguments as questions of “weight,” not admissibility, but as Defendants explained in their opening brief, McCann’s dubious application of the assumption goes directly to admissibility.

First, McCann, relying on Rafalski, assumes incorrectly that Defendants had a duty to investigate the specific order that first “triggered” the SMTT methodology, and then based on the further assumption that no due diligence occurred on that order, flags all subsequent orders as

suspicious regardless of their size in relation to the SMTT. Br. 12; Opp. 13. Of course, as Plaintiffs concede, no Defendant used or had an obligation to use SMTT, *see* Opp. 22, 27, so the order that *he* first flagged with that method may not have been flagged under the different methodologies Defendants actually used. By nevertheless using that order as the basis on which tens of thousands of subsequent orders are flagged, plaintiffs contradict themselves by attempting to punish defendants for not using a methodology they concede no defendant was required to follow.

Second, McCann’s application of the assumption is not appropriately validated. McCann assumes no due diligence, but neither he nor Rafalski analyzed whether Defendants in fact failed to review the particular orders or customers, or any subsequent orders to that customer. McCann did not review “any documents or deposition testimony . . . to validate the assumption.”¹⁰ Rafalski acknowledged that if a distributor conducted due diligence on a flagged order, then the assumption should not be applied.¹¹ By the same logic, if defendants’ actual methods were flagging different orders, which were then reviewed and determined not to be suspicious, then there would be no basis for using an assumption to flag all subsequent orders thereafter. But when asked whether he reviewed “particular orders on particular days . . . sent by particular pharmacies to distributors,” Rafalski conceded that he did not.¹² The practical implication is that the jury will be told that Defendants conducted no due diligence on any of the flagged orders, even though plaintiffs’ own experts purposefully failed to investigate whether that was true.

For these reasons, McCann’s application of the assumption was unfounded and dramatically inflated the number of flagged orders from around 5% to more than 90%. Because

¹⁰ McCann Tr. 286:15–19.

¹¹ Rafalski Tr. (Dkt. 1983-15) 186:21–187:18.

¹² Rafalski Tr. 197:21–198:3 (stating his analysis did not entail “looking at each order by order”). Rafalski did not even have access to McCann’s raw data and could not know which particular orders were flagged. *See supra* at 8.

his application of this assumption does not reflect either the legal duties actually owed by Defendants or valid opinion regarding the steps Defendants actually took to investigate orders and the customers who placed them, orders flagged due to this assumption should not be presented to the jury.

* * * * *

Plaintiffs wrongly suggest that Defendants’ position is that “there is no reliable way to determine which orders should have been flagged.” Opp. 3. Not so. Plaintiffs might have chosen a number of ways to identify suspicious orders consistent with legal duties that Defendants actually owed. Indeed, the most reliable way would have been the one DEA has *repeatedly* advised: by analyzing the totality of circumstances, on an order-by-order and customer-by-customer basis. Plaintiffs opted instead to identify orders (i) using a single-variable, one-size-fits-all algorithm that (ii) no Defendant used or was required to use, and (iii) to apply unvetted assumptions in order to drive the numbers high enough to justify their demand for billions of dollars. These opinions have no basis in the CSA, the common law, or any other source of legal duty owed by Defendants, and accordingly fail to fit the facts of the case.

II. Plaintiffs Fail to Justify the Other Defects in McCann’s Analysis.

Specific methodologies. Methods B and C purport to analyze systems “used by Defendants themselves,” but Plaintiffs’ discussion shows why that is highly misleading, at least as to certain Defendants. McCann applied thresholds by lumping all pharmacies together—big or small—and then multiplying the average order volume by 2 or 3. But as Plaintiffs acknowledge, Defendants’ systems were different and used a more sophisticated threshold-setting methodology. For example, according to Plaintiffs, Cardinal Health segmented customers “by size and/or specialty” and applied different thresholds accordingly, an approach Rafalski himself acknowledged was

appropriate but which is not reflected by Methods B or C.¹³ Moreover, *no* defendant used the assumption that *all* orders following an initial flagged order should also be flagged.

Plaintiffs argue that the Maximum Daily Dosage Unit method is extensively discussed in Rafalski's report, but that was not Defendants' argument. Defendants argued that this method was not disclosed in Plaintiffs' interrogatory responses, where Plaintiffs were required to disclose the methods they were using, and which Rafalski testified included his five methods.

Aggregate flagging. Plaintiffs reject that McCann presented his flagging analyses only in the aggregate because "Plaintiffs provided Defendants with the Excel files used to generate those charts and tables." Opp. 26. This argument misses the point. The only flagging analyses that were available to *Rafalski* were the aggregated charts. Whether or not Defendants could have done it, Rafalski could not—and did not—analyze particular orders with only the aggregated data.

National averages. Plaintiffs assert that McCann used national averages for some Defendants and county averages for others, depending on what data was available. Opp. 26. That is false. McCann had national data for most of the Defendants, but used national averages only for two: Walmart and CVS. McCann certainly had national data for defendants like Cardinal, ABDC, McKesson, or Walgreens because DEA produced a dozen years of national ARCOS data. Rafalski's methods explicitly call for the use of national—not county—averages. Plaintiffs do not dispute that how an average is calculated affects the thresholds that McCann calculates. Plaintiffs have essentially conceded this point and have therefore failed to meet their burden to show that McCann's use of county averages is reliable under *Daubert*.

CONCLUSION

This Court should exclude the opinions and testimony of Craig McCann.

¹³ Rafalski Rpt. at 37–38.

Dated: August 16, 2019

Respectfully submitted,

/s/ Mark S. Cheffo

Mark S. Cheffo
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Mark.Cheffo@dechert.com

*Counsel for Defendants Purdue Pharma L.P.,
Purdue Pharma Inc., and The Purdue Frederick
Company*

*Co-Liaison Counsel for the Manufacturer
Defendants¹⁴*

/s/ Carole S. Rendon

Carole S. Rendon
BAKER & HOSTETLER LLP
Key Tower 127 Public Square, Suite 2000
Cleveland, OH 44114-1214
Telephone: (216) 621- 0200
Fax: (216) 696-0740
crendon@bakerlaw.com

*Counsel for Defendants Endo Health Solutions Inc.
and Endo Pharmaceuticals Inc.; Par
Pharmaceutical, Inc., and Par Pharmaceutical
Companies, Inc.*

*Co-Liaison Counsel for the Manufacturer
Defendants*

¹⁴ Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

/s/ Enu Mainigi
WILLIAMS & CONNOLLY LLP
Enu Mainigi
725 Twelfth Street, N.W.
Washington, DC 20005
Telephone: (202) 434-5000
Fax: (202) 434-5029
emainigi@wc.com

Counsel for Defendant Cardinal Health, Inc.

Co-Liaison Counsel for the Distributor Defendants

/s/ Shannon E. McClure
Shannon E. McClure
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Telephone: (215) 851-8100
Fax: (215) 851-1420
smcclure@reedsmith.com

*Counsel for Distributor Defendant
AmerisourceBergen Drug Corporation*

Co-Liaison Counsel for the Distributor Defendants

/s/ Geoffrey Hobart
Geoffrey Hobart
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
Telephone: (202) 662-5281
ghobart@cov.com

*Counsel for Distributor Defendant
McKesson Corporation*

Co-Liaison Counsel for the Distributor Defendants

/s/ Kaspar Stoffelmayr _____

Kaspar Stoffelmayr
BARTLIT BECK LLP
54 West Hubbard Street
Chicago, IL 60654
Telephone: (312) 494-4434
Fax: (312) 494-4440
kaspar.stoffelmayr@bartlitbeck.com

Counsel for the Walgreens Defendants

*Liaison Counsel for the Chain Pharmacy
Defendants*

CERTIFICATE OF SERVICE

I, Ashley W. Hardin, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Ashley W. Hardin
Ashley W. Hardin